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Pabst Patent Group LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, GA 30361

Telephone (404) 879-2150
Telefax (404) 879-2160

information@pabstpatent.com
www.pabstpatent.com

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Date: October 24, 2005

Total pages: 25 (incl. cover sheet)

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Our Docket No. VAC 104 CON
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Charles A. Vacanti and Martin P. Vacanti

Serial No.: 10/792,302 Art Unit: 1651

Filed: March 3, 2004 Examiner: L.B. Lankford, Jr.

For: *ISOLATION OF SPORE-LIKE CELLS FROM TISSUES EXPOSED TO EXTREME CONDITIONS*

Attachments
PTO/SB/21 Transmittal Form;
PTO/SB/17 Fee Transmittal,
Appeal Brief

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Application Number	10/792,302
Filing Date	March 3, 2004
First Named Inventor	Charles A. Vacanti
Art Unit	1651
Examiner Name	L.B. Lankford, Jr.
Attorney Docket Number	VAC 104 CON

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Charles A. Vacanti and Martin P. Vacanti

Serial No.: 10/792,302 Art Unit: 1651

Filed: March 3, 2004 Examiner: L.B. Lankford Jr.

For: ISOLATION OF SPORE-LIKE CELLS FROM TISSUES EXPOSED TO EXTREME CONDITIONS

Commissioner for Patents
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an appeal of the rejection of the claims in the Office Action mailed on February 25, 2005. A response was filed on July 25, 2005, but despite numerous calls to the examiner and his supervisor, the undersigned has not been able to determine if the amendment filed with the response has been entered. Accordingly, in order to avoid extension of time fees which would unfairly burden appellants, this Appeal Brief is being filed as if the amendment had been entered. The fee for a small entity for filing the brief accompanies this Appeal Brief. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

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(1) REAL PARTIES IN INTEREST

The real parties in interest of this application are the assignee, VBI Technologies, L.L.C.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellant, the undersigned, or appellant's assignee which directly affects, which would be directly affected by, or which would have a bearing on, the Board's decision in this appeal.

(3) STATUS OF CLAIMS ON APPEAL

Claims 1-27 are pending and on appeal.

(4) STATUS OF AMENDMENTS

A response and amendment was filed on July 25, 2005. Despite multiple phone calls to the examiner and message to the supervisor, appellants have not received any response to this amendment. It has therefore been assumed that the amendment was entered (PAIR shows it received by the examiner almost three months ago, August 1, 2005) and that the rejections remain outstanding. An appendix sets forth the claims on appeal.

(5) SUMMARY OF THE INVENTION

Claim 1 defines a method for isolating a pluripotent or multipotent spore-like cell population from a mammalian biological tissue or cell containing fluid, the method comprising (a) obtaining a mammalian tissue or cell containing fluid and exposing the mammalian tissue or cell containing fluid to an environment in which differentiated or partially differentiated cells in the tissue or fluid die (*see* page 3, lines 15-17), wherein

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the environment includes one or more conditions selected from the group consisting of temperature of 42°C or greater, freezing, non-physiological salt concentration (*see* page 3, lines 26-31; page 4, lines 1-8; page 20 lines 6-10), essential absence of oxygen for at least four hours (*see* page 18, lines 5-8), size separation (*see* page 7, lines 7-12) and passaging in cell culture, treatment with acid or base, radiation and drying (*see* page 20, lines 6-10), and (b) separating the population of viable spore-like cells from the dead differentiated or partially differentiated cells (*see* page 6, lines 29-31 and page 7, lines 1-2). These are not stem cells (*see* page 24, lines 11-18; page 2, line 22). Isolation from tissue is found at page 2, bottom of page 4, top of page 7, and in the examples. Although there is no reason to believe these cell populations can only be isolated from mammals, the claims have been limited to mammalian cells since all of the examples relate to mammals – rats, sheep, humans. Support is found for the term "mammalian" at page 37, line 8.

Dependent claims further define the method of isolation: claim 2, the method further comprising disrupting the tissue or fluid either before or after step (a) and separating the viable spore-like cell from the dead differentiated or partially differentiated cells by size separation (*see* page 7, lines 12-14 and 20-24); claim 7 wherein the tissue or fluid is treated with salt, acid or base and the spore-like cells isolated; claim 8, wherein the biological tissue comprises a tissue that originates from the endoderm (*see* page 8, lines 28-29); claim 9, wherein the biological tissue comprises a tissue that originates from the mesoderm (*see* page 8, lines 28-29); claim 10, wherein the biological tissue comprises a tissue that originates from the ectoderm (*see* page 8, lines 28-29); claim 11, wherein the

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biological fluid comprises blood, urine, or saliva (*see* page 14, lines 14-17); claim 12 , wherein the biological fluid is cerebrospinal fluid (*see* page 14, lines 14-17); claim 13, wherein the environment is an oxygen-poor environment (*see* page 2, lines 29-31); claim 14, wherein the environment is one in which the temperature is above or below the range of temperatures in which differentiated or partially differentiated cells can survive (*see* page 3, lines 26-27); claim 15, wherein the environment contains a toxin or infectious agent that kills differentiated or partially differentiated cells (*see* page 6, lines 14-16); claim 16, wherein the environment contains radiation or is dessicating (*see* page 6, lines 14-17); and claim 27, wherein the biological fluid is cerebrospinal fluid (*see* page 14, lines 14-17).

Dependent claims also further define properties of the isolated cell population: claim 3, wherein the spore-like cell population fails to demonstrate activity in a microtetrazolium assay; claim 4, wherein the spore-like cells contain between approximately 50 and 90% by volume nuclear material (*see* page 15, lines 15-17); claim 5, wherein the spore-like cells have a diameter of approximately 15 microns or less (*see* page 7, line 10); claim 6, wherein the spore-like cells have a diameter of between 0.1 and 3.0 microns (*see* page 19, line 31 and page 20, lines 1-4).

Dependent claims define a further step in which the cells are placed in a matrix for tissue repair or regeneration, and wherein the matrix is implanted: claim 17, where the method of claim 1 further comprising placing the cell population into a matrix for implantation into a site for tissue repair, augmentation or regeneration (*see* page 24, line 30 until page 25, line 5 and page 12, lines 18-19); claim 18, the method of claim 17,

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further comprising implanting the matrix into a site for tissue repair, augmentation or regeneration (*see* page 24, line 30 until page 25, line 5 and page 12, lines 18-19); claim 20, the method of claim 18 further comprising implanting the matrix into a tissue selected from the group consisting of the visual system, auditory system, nasal epithelium, alimentary canal, pancreas, gallbladder, bladder, kidney, liver, heart, respiratory system, nervous system, reproductive system, endocrine system, immune system, bone, muscle, tooth, nail, and skin (*see* page 8, lines 18-25); claim 21, the method of claim 17 wherein the matrix is a hydrogel (*see* page 9, lines 21-22); claim 22, wherein the tissue is one of cardiac, smooth and skeletal muscle, intestine, bladder, kidney, liver, lung, adrenal gland, skin, retina, nasal epithelium, brain, spinal cord, periosteum, perichondrium, fascia, or pancreas (*see* page 14, lines 14-17); claim 25, the method of claim 21 wherein the spore-like cells in the population are introduced into a support structure; claim 26, the method of claim 17 wherein the matrix is a porous polymer mesh, suture, film or sponge (*see* page 30, lines16-17).

Dependent claims also define further processing steps: claim 19, the method of claim 1 further comprising culturing the spore-like cell population (*see* page 6, lines 10-11); claim 23, the method of claim 1 wherein the spore-like cell population is frozen after isolation (*see* page 6, lines 25-26); claim 24, the method of claim 1 further comprising inducing the isolated spore-like cells in the population to differentiate(*see* page 6, lines 25-26)

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(6) ISSUES ON APPEAL

The issues presented on appeal are:

(1) whether claims 1-27 meet the written description and definiteness requirements under 35 U.S.C. § 112, first paragraph.

(7) GROUPING OF CLAIMS

The claims do not stand or fall together, as discussed below.

(8) ARGUMENTS

A. The Invention

Appellants have isolated a population of multipotent mammalian cells from tissue or a tissue derived cell suspension; not a single cell. These are not stem cells (see page 24, lines 11-18). Therefore the claims have been amended to recite these features, as suggested by the examiner's supervisor. Support for multipotent cells is found, for example, at page 2, line 22. Isolation from tissue is found at page 2, bottom of page 4, top of page 7, and in the examples. Although there is no reason to believe these cell populations can only be isolated from mammals, the claims have been limited to mammalian cells since all of the examples relate to mammals – rats, sheep, humans Support is found for the term "mammalian" at page 37, line 8.

The claims have been amended to define the claimed subject matter as a method for isolating this population of cells. As was emphasized during the interview by Dr. Vacanti, the method for separating spore-like cells from differentiated cells, includes exposing a mixture of the cells to conditions that kill the differentiated cells but not the spore-like cells. Independent claim 1 was previously amended to define the conditions

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that kill normal differentiated cells but not the spore-like cells. The dependent claims now more specifically also define the features of the cells, such as the amount of nuclear material, the size, and the lack of differentiation. These conditions are found at page 6, lines 12-29; page 15, lines 19-23; page 18, lines 1-25 (conditions to kill differentiated cells), page 7, lines 7-12 (separation by filtration); page 14, lines 20-28 (spore like cells are multipotent); page 14, line 29 to page 15, line 2; page 15, lines 15-18; page 16, line 29 to page 17, line 17; see also Figures 1 and 2 (size, amount of nucleus).

B. Rejections under 35 U.S.C. § 112

Claims 1-27 were rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement and definiteness.

1. Legal Requirements

In *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 at 920, 69 USPQ 1886 (Fed. Cir. 2004), the Federal Circuit reviewed the standard of the written description requirement under 35 U.S.C. 112 and reiterated that the purpose of the written description requirement is separate from the enablement requirement, and "is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventors's contribution to the field of art as described in the patent specification,' *Reiffin v. Microsoft Corp.*, 214 F.3d 1342 at 1345 (Fed. Cir. 2000). "The 'written description' requirement serves a teaching function, as a '*quid pro quo*' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time', citing to *Enzo Biochem, Inc. v. Gen-Probe Inc*, 323 F.3d 956 at 970 (Fed. Cir. 2002). *University of Rochester* at 922.

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The law has long allowed an applicant to claim all that he is entitled to, not forcing him to limit his claims to a specific example, if other means for achieving the same step would be known to those skilled in the art and not require undue experimentation. That is clearly the case here. "There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed". *Wertheim*, 541 F.2d at 262, 191 USPQ at 96 (CCPA 1976). The written description requirement for a claimed genus may be satisfied through a sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or a disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

The claims satisfy the written description requirement. In *Schering Corp v. Gilbert*, the court noted that it cannot be doubted that the claim itself must not be divorced in a vacuum from the specifications and descriptions accompanying it (See, e.g., *Schering Corp v. Gilbert* 397 F.2d at 664, 157 USPQ at 557). The law has long allowed an applicant to claim all that he is entitled to, not forcing him to limit his claims to a specific example, if the means for achieving the method would be known to those skilled in the art and not require undue experimentation. That is clearly the case here. The written description requirement for a claimed genus may be satisfied through a sufficient

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description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or a disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. As affirmed by the Court in *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524 (Fed. Cir. 1987), a patent need not teach, and preferably omits, what is well known in the art. Furthermore, it is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art." In *Ex parte Obukowicz*, 27 U.S.P.Q.2d (BNA) 1063, 1067 (P.O.B.A.I 1993). To be definite, the claims must define to one skilled in the art the metes and bounds of the claimed subject matter.

2. The specification and claims comply with the legal requirements for written description and definiteness

The principal basis of the rejection was that the spore-like cells are not clearly defined. It is believed this aspect of the rejection has been mooted by defining the method as one which isolates a multipotent cell population using conditions that are used to kill the differentiated cells but not the spore-like cells, and defining the distinguishing characteristic separating the two types of cell as that multi- or pluripotent spore-like cells remain viable when exposed to the specific conditions, and the differentiated cells do not, as well as by describing in the specification the size, nuclear structure, and

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phenotypic characteristics of the spore-like cells, including actual SEMs of these cells from different tissues of origin (see examples 11 and 12, page 38).

Claim 1 defines a method for isolating a pluripotent or multipotent spore-like cell population from a mammalian biological tissue or cell containing fluid, the method comprising (a) obtaining a mammalian tissue or cell containing fluid and exposing the mammalian tissue or cell containing fluid to an environment in which differentiated or partially differentiated cells in the tissue or fluid die, wherein the environment includes one or more conditions selected from the group consisting of temperature of 42°C or greater, freezing, non-physiological salt concentration, essential absence of oxygen for at least four hours, size separation and passaging in cell culture, treatment with acid or base, radiation and drying, and (b) separating the population of viable spore-like cells from the dead differentiated or partially differentiated cells. These are not stem cells (see page 24, lines 11-18; page 2, line 22). Isolation from tissue is found at page 2, bottom of page 4, top of page 7, and in the examples. Although there is no reason to believe these cell populations can only be isolated from mammals, the claims have been limited to mammalian cells since all of the examples relate to mammals – rats, sheep, humans. Support is found for the term "mammalian" at page 37, line 8.

Dependent claims further define the method of isolation: claim 1, the method further comprising disrupting the tissue or fluid either before or after step (a) and separating the viable spore-like cell from the dead differentiated or partially differentiated cells by size separation; claim 7 wherein the tissue or fluid is treated with salt, acid or base and the spore-like cells isolated; claim 8, wherein the biological tissue comprises a

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tissue that originates from the endoderm; claim 9, wherein the biological tissue comprises a tissue that originates from the mesoderm; claim 10, wherein the biological tissue comprises a tissue that originates from the ectoderm; claim 11, wherein the biological fluid comprises blood, urine, or saliva; claim 12, wherein the biological fluid is cerebrospinal fluid; claim 13, wherein the environment is an oxygen-poor environment; claim 14, wherein the environment is one in which the temperature is above or below the range of temperatures in which differentiated or partially differentiated cells can survive; claim 15, wherein the environment contains a toxin or infectious agent that kills differentiated or partially differentiated cells; claim 16, wherein the environment contains radiation or is dessicating; and claim 27, wherein the biological fluid is cerebrospinal fluid. Each of these method steps is readily ascertainable by those skilled in the art. One would have no trouble determining the metes and bounds of the claimed method.

Dependent claims define a further step in which the cells are placed in a matrix for tissue repair or regeneration, and wherein the matrix is implanted: claim 17, where the method of claim 1 further comprising placing the cell population into a matrix for implantation into a site for tissue repair, augmentation or regeneration; claim 18, the method of claim 17, further comprising implanting the matrix into a site for tissue repair, augmentation or regeneration; claim 20, the method of claim 18 further comprising implanting the matrix into a tissue selected from the group consisting of the visual system, auditory system, nasal epithelium, alimentary canal, pancreas, gallbladder, bladder, kidney, liver, heart, respiratory system, nervous system, reproductive system, endocrine system, immune system, bone, muscle, tooth, nail, and skin; claim 21, the

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method of claim 17 wherein the matrix is a hydrogel; claim 22, wherein the tissue is one of cardiac, smooth and skeletal muscle, intestine, bladder, kidney, liver, lung, adrenal gland, skin, retina, nasal epithelium, brain, spinal cord, periosteum, perichondrium, fascia, or pancreas; claim 25, the method of claim 21 wherein the spore-like cells in the population are introduced into a support structure; claim 26, the method of claim 17 wherein the matrix is a porous polymer mesh, suture, film or sponge. These all define methods and materials for use with the cell population obtained as defined by claims 1-16, which would be clear to those skilled in the art.

Dependent claims also define further processing steps: claim 19, the method of claim 1 further comprising culturing the spore-like cell population; claim 23, the method of claim 1 wherein the spore-like cell population is frozen after isolation; claim 24, the method of claim 1 further comprising inducing the isolated spore-like cells in the population to differentiate. One skilled in the art would have no trouble understanding the scope of these claimed method steps.

Dependent claims also further define properties of the isolated cell population, adding further definiteness to the products of the claimed method: claim 3, wherein the spore-like cell population fails to demonstrate activity in a microtetrazolium assay; claim 4, wherein the spore-like cells contain between approximately 50 and 90% by volume nuclear material; claim 5, wherein the spore-like cells have a diameter of approximately 15 microns or less; claim 6, wherein the spore-like cells have a diameter of between 0.1 and 3.0 microns. In the event one could not ascertain the metes and bounds of the method of claim 1, based on the resulting isolated cell population, claims 3-6 add further

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definition and clarity based on specific and readily measurable features of the cells in the isolated population.

The examiner has not made an enablement rejection, but relied instead on lack of clarity and written description. To the extent a lack of enablement rejection was intended or could be raised, the examples clearly demonstrate that the claimed method was actually reduced to practice with a variety of different means of killing the differentiated cells but not the spore-like cells, and that the cells could then be separated. This fully complies with the written description requirement. Indeed, the specification not only shows that the appellants were in possession of the claimed method, but had reduced it to practice on multiple occasions.

Example 1 demonstrates that spore-like cells were isolated from human blood (first species, first cell type) using repeated passaging in cell culture.

Example 2 demonstrates that spore-like cells were isolated from rat (species 2) skin (second cell type). The technique used for all of examples 2-10 was size separation (passaging through smaller and smaller bore pipets) followed by passaging in cell culture.

Example 3 demonstrates that spore-like cells were isolated from rat heart (third cell type).

Example 4 demonstrates that spore-like cells were isolated from rat intestine (fourth cell type) .

Example 5 demonstrates that spore-like cells were isolated from rat bladder (fifth cell type) 2.

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Example 6 demonstrates that spore-like cells were isolated from rat kidney (sixth cell type).

Example 7 demonstrates that spore-like cells were isolated from rat liver (seventh cell type).

Example 8 demonstrates that spore-like cells were isolated from sheep (third species) and rat lungs (eight cell type).

Example 9 demonstrates that spore-like cells were isolated from rat adrenal glands (ninth cell type).

Example 10 demonstrates that spore-like cells were isolated from human and rat pancreas (tenth cell type).

Examples 13 and 14 demonstrates that spore-like cells were isolated from rat lung, liver, fascia, and spinal cord (four tissues, including two additional cell types) using enzyme digestion, storage in the refrigerator or freezer without supplemental oxygen (second technique) and passage through smaller and smaller pipets.

Example 15 demonstrates that spore-like cells were isolated from rat lung, liver, fascia, and spinal cord by heating to 85°C (third technique). Trypan blue uptake was used to differentiate the viable from the dead cells.

Example 17 demonstrates isolation of spore-like cells from human blood that had been stored frozen for eight years and then were repeatedly frozen and unfrozen, and separated by passage through filters and pasteur pipets.

In summary, spore-like cell populations were isolated using three completely different techniques: size separation and passage through cell culture; storage in the

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substantial absence of oxygen; and heating. Spore-like cells were isolated from three different species: human, rat and sheep. Finally, spore-like cells were isolated from twelve different cell types: blood, lung, liver, adrenal gland, fascia, spinal cord, skin, pancreas, kidney, bladder, intestine, and heart. The cells were characterized functionally, histologically, by SEM, and by phenotype.

(9) SUMMARY AND CONCLUSION

The claims provide a simple, easy and definitive means for practicing the method: one simply performs one or more of the recited means for killing differentiated cells but not spore-like cells, and then retains the viable cells, which are by definition the spore-like cells. It is believed that appellants have fully and adequately responded to each basis of concern raised by the examiner. The claims are definite and comply with the written description requirement.

Allowance of claims 1-27 is respectfully solicited.

Respectfully submitted,

Patrea L. Pabst
Reg. No. 31,284

Date: October 24, 2005
PABST PATENT GROUP LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, Georgia 30361
(404) 879-2151
(404) 879-2160 (Facsimile)

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APPENDIX: Claims

1. (previously presented) A method for isolating a pluripotent or multipotent spore-like cell population from a mammalian biological tissue or cell containing fluid, the method comprising (a) obtaining a mammalian tissue or cell containing fluid and exposing the mammalian tissue or cell containing fluid to an environment in which differentiated or partially differentiated cells in the tissue or fluid die, wherein the environment includes one or more conditions selected from the group consisting of temperature of 42°C or greater, freezing, non-physiological salt concentration, essential absence of oxygen for at least four hours, size separation and passaging in cell culture, treatment with acid or base, radiation and drying, and

(b) separating the population of viable spore-like cells from the dead differentiated or partially differentiated cells.

2. (previously presented) The method of claim 1, further comprising disrupting the tissue or fluid either before or after step (a) and separating the viable spore-like cell from the dead differentiated or partially differentiated cells by size separation.

3. (previously amended) The method of claim 1 wherein the spore-like cell population fails to demonstrate activity in a microtetrazolium assay.

4. (previously presented) The method of claim 1 wherein the spore-like cells contain between approximately 50 and 90% by volume nuclear material.

5. (previously presented) The method of claim 1 wherein the spore-like cells have a diameter of approximately 15 microns or less.

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6. (previously presented) The method of claim 1 3, wherein the spore-like cells have a diameter of between 0.1 and 3.0 microns.

7. (previously presented) The method of claim 1 wherein the tissue or fluid is treated with salt, acid or base and the spore-like cells isolated.

8. (original) The method of claim 1, wherein the biological tissue comprises a tissue that originates from the endoderm.

9.(original) The method of claim 1, wherein the biological tissue comprises a tissue that originates from the mesoderm.

10. (original) The method of claim 1, wherein the biological tissue comprises a tissue that originates from the ectoderm.

11. (original) The method of claim 1, wherein the biological fluid comprises blood, urine, or saliva.

12. (original) The method of claim 1, wherein the biological fluid is cerebrospinal fluid.

13. (original) The method of claim 1, wherein the environment is an oxygen-poor environment.

14. (original) The method of claim 1, wherein the environment is one in which the temperature is above or below the range of temperatures in which differentiated or partially differentiated cells can survive.

15. (original) The method of claim 1, wherein the environment contains a toxin or infectious agent that kills differentiated or partially differentiated cells.

16. (previously presented) The method of claim 1 wherein the environment contains radiation or is dessicating.

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17. (previously amended) The method of claim 1 further comprising placing the cell population into a matrix for implantation into a site for tissue repair, augmentation or regeneration.

18. (previously presented) The method of claim 17, further comprising implanting the matrix into a site for tissue repair, augmentation or regeneration.

19. (previously amended) The method of claim 1 further comprising culturing the spore-like cell population.

20. (previously presented) The method of claim 18 further comprising implanting the matrix into a tissue selected from the group consisting of the visual system, auditory system, nasal epithelium, alimentary canal, pancreas, gallbladder, bladder, kidney, liver, heart, respiratory system, nervous system, reproductive system, endocrine system, immune system, bone, muscle, tooth, nail, and skin.

21. (previously presented) The method of claim 17 wherein the matrix is a hydrogel.

22. (previously amended) The method of claim 1 wherein the tissue is selected from the group consisting of cardiac, smooth and skeletal muscle, intestine, bladder, kidney, liver, lung, adrenal gland, skin, retina, nasal epithelium, brain, spinal cord, periosteum, perichondrium, fascia, and pancreas.

23. (previously amended) The method of claim 1 wherein the spore-like cell population is frozen after isolation.

24. (previously amended) The method of claim 1 further comprising inducing the isolated spore-like cells in the population to differentiate.

25. (previously amended) The method of claim 21 wherein the spore-like cells in the

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population are introduced into a support structure.

26. (previously presented) The method of claim 17 wherein the matrix is a porous polymer mesh, suture, film or sponge.

27. (previously presented) The method of claim 1, wherein the biological fluid is cerebrospinal fluid.

Claims 28 and 29. (Cancelled)

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APPENDIX 2: Related Proceedings

There are no related proceedings.

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APPENDIX: Copies of Previously Submitted Evidence

No evidence other than that submitted in the examples in the application has been filed.

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